

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DUB

2.16.99
....." 2 Date 2.17
Certifier C. Loms-D

21 CFR Part 179

[Docket No. 98 N-1038]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering proposing revisions of its labeling requirements for foods treated with ionizing radiation. FDA is publishing this advance notice of proposed rulemaking (ANPRM) in response to the direction given in the Joint Explanatory Statement of the Committee of Conference that accompanied the Food and Drug Administration Modernization Act of 1997 (FDAMA). The FDAMA Joint Statement directed FDA to publish for public comment proposed changes to current regulations relating to the labeling of foods treated with ionizing radiation. As a first step, the agency is making available to the public, through this document, various documents including the relevant text from the FDAMA Joint Statement; prior FDA rulings regarding food irradiation; recent submissions to FDA regarding the labeling of irradiated foods, including a citizen petition; a report of a meeting attended by FDA representatives at which labeling of irradiated foods was discussed; and other relevant materials. The agency encourages interested persons to submit comments, including pertinent data and information, to aid FDA's consideration of revisions to the labeling requirements for irradiated foods.

DATES: Written comments must be submitted by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments and supporting material to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St, SW., Washington, DC 20204, 202-418-3093.

SUPPLEMENTARY INFORMATION:

I. Introduction

Through a series of proceedings under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21U.S.C. 348), FDA has approved the use of ionizing radiation on various foods under specific conditions. These approvals are codified in FDA's regulations at §179.26 (21 CFR 179.26).¹ The agency's regulations require that the label and labeling of retail packages or displays of foods treated with ionizing radiation include both the radura logo (the international symbol that indicates radiation treatment) and a disclosure statement (either "Treated with radiation" or "Treated by irradiation") in addition to information required by other regulations (§ 179.26(c)(1) and (c)(2)). The regulations require that the logo be placed prominently and conspicuously in conjunction with the required statement.

On November 21, 1997, President Clinton signed FDAMA into law (Pub. L. 105–1 15). Section 306 of FDAMA amended the act by adding section 403C (21 U.S.C. 342-3). Section 403C of the act addresses the disclosure of irradiation on the labeling of food as follows:

(a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

¹ Two of FDA's most recent approvals authorized the use of irradiation to reduce microbial pathogens on meat and poultry. Recently, the use of irradiation has received increased attention as an important potential tool for reducing foodborne illness.

(b) In this section, the term ‘radiation disclosure statement’ means a written statement that discloses that a food has been intentionally subject to irradiation.

Although FDA’s regulations did not specify how prominent a radiation disclosure must be, the agency concluded there was merit to having the regulation in §179.26 include the prominence specification of the new statutory provision. Accordingly, in the **Federal Register** of August 17, 1998 (63 FR 43875), FDA amended its labeling requirement for irradiated foods to state that a radiation disclosure statement is not required to be any more prominent than the declaration of ingredients required under section 403(i)(2) of the act.

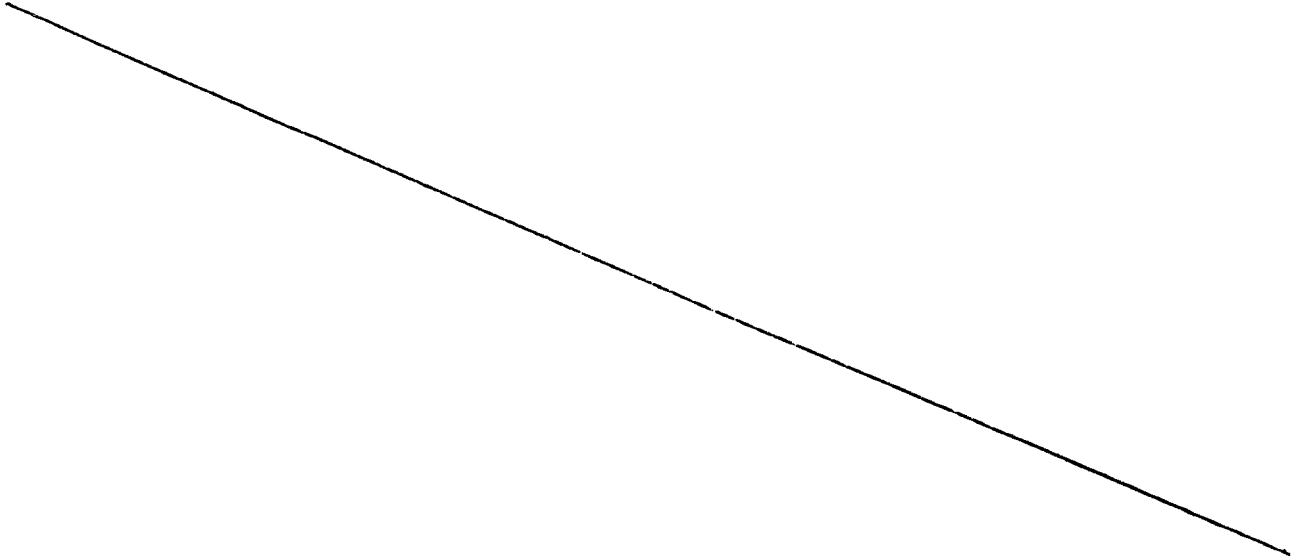
Although section 403C of the act addressed only the prominence of the radiation disclosure statements, the language in the FDAMA Joint Statement (H. Rept. 105–399, 105th Cong., 1st sess., at 98–99) directed FDA to publish for public comment proposed changes to current regulations relating to labeling of foods treated with ionizing radiation. Specifically, the Joint Statement directed that, “The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. ” The FDAMA Joint Statement also indicated that, “The conferees intend for any required irradiation disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. ” (Ref. 1.)

FDA notes that the law requires that irradiation labeling statements, like other labeling statements, be truthful and not misleading (403(a)(1) of the act). The agency also notes that over the years, it has received letters expressing a variety of views regarding the labeling of irradiated foods. However, at this time, FDA is not aware of a consensus regarding specific changes in the labeling of irradiated food that would best accomplish the intent of the conferees and also satisfy the requirements of the act and other agency regulations regarding the labeling of food in general. Therefore, the agency is publishing this ANPRM to request public comment on whether revisions

to the current labeling requirements for irradiated foods are needed to accomplish these objectives and, if so, what form such revisions might take.

II. Background on FDA's Labeling Requirements for Irradiated Foods

As noted, over the years, FDA has issued several rules that address the labeling of irradiated foods. In the **Federal Register** of February 14, 1984 (49 FR 5714), FDA published a proposal to approve the use of ionizing radiation on several foods; that proposal did not include a requirement for labeling disclosing the use of ionizing radiation (Ref. 2). The agency received over 5,000 comments on this proposal, among them, numerous comments on the issue of labeling irradiated foods. Based on the comments and information received in response to the 1984 proposal and on further analysis, FDA published a final rule in the **Federal Register** of April 18, 1986 (51 FR 13376) (the 1986 rule), requiring that the labeling of retail packages and displays of irradiated food bear both the radura logo and a radiation disclosure statement (Ref. 3). The agency had concluded that labeling indicating treatment of food with radiation was necessary to prevent misbranding of irradiated foods. In response to the 1986 rule, FDA received various submissions commenting on, and objecting to, different aspects of that rule, including the labeling requirements. In the **Federal Register** of December 30, 1988 (53 FR 53176) (the 1988 response to objections), FDA discussed several comments and objections to the labeling requirements of the 1986 rule



and concluded that the information submitted in the comments and objections provided no basis to change those requirements. Thus, the agency reaffirmed its earlier decision (Ref. 4).²

In the preamble to the 1986 rule, FDA emphasized that the required label statement (‘‘Treated with radiation’’ or ‘‘Treated by irradiation’’) could be augmented by optional statements that describe the type of radiation used or explain the reason for irradiation, provided such statements were truthful and not misleading. That is, manufacturers could include in product labeling statements such as ‘‘treated with X-radiation’’ or ‘‘treated with electron beam radiation,’’ provided that the more specific description was applicable. Similarly, manufacturers could include statements such as ‘‘treated with radiation to extend shelf-life’’ or ‘‘treated by irradiation to control pathogens,’’ provided the more specific statement truthfully described the primary purpose of the treatment (Ref. 3).

² As discussed in both the 1986 final rule and the 1988 response to objections, FDA concluded that **labeling** of irradiated foods was necessary because such processing is a material fact that must be disclosed to the consumer to prevent deception. The agency determined that irradiation is a form of processing that can produce significant changes in certain characteristics of a food, such as the organoleptic (e.g., taste, smell, texture) or holding properties, in a manner that is not obvious to the consumer in the absence of labeling. That is, in the absence of **labeling** indicating that the food has been irradiated, the implied representation to consumers is that the food has not been processed.

On the other hand, FDA recognized that irradiation of an ingredient in a multiple ingredient food represented a different situation because such a food has obviously been processed, and concluded that consumers would not need special labeling to recognize that fact. Therefore, the agency did not require special labeling of a food that contained an irradiated ingredient but that had not itself been irradiated. FDA also concluded that the **labeling** requirements for irradiated ingredients in a multiple ingredient food should be the same as for any other processed ingredients, namely, that they be declared by their common or usual name without any requirement for stating whether they were processed (see 51 FR 13376 at 13389 and 53 FR 53176 at 53205).

FDA further concluded that the best way to convey to consumers the factual information that a food had been irradiated was to require labeling with the radura logo, which would indicate that the food had been processed by irradiation (but which would not be interpreted as a warning or erroneously associated with the idea that radioactivity is in the food). However, because the radura logo was not in common use at that time and, thus would not be recognized, FDA also required a disclosure statement, linked with the radura, so that consumers would understand its meaning. At that time, the agency believed that consumer awareness of irradiated foods and the meaning of the radura logo would increase as irradiated foods entered the marketplace and that, in time, a separate disclosure statement would no longer be necessary. Thus, the requirement for a separate disclosure statement initially was to expire on April 18, 1988. However, the agency subsequently extended the requirement for a disclosure statement (Ref. 5:53 FR 12757, April 18, 1988) and later made the requirement permanent (Ref. 6:55 FR 14415, April 18, 1990), having determined, at that time, that the public was not sufficiently familiar with the meaning of the radura logo for it to be used without a statement.

III. Other Views on Labeling Requirements for Irradiated Foods

FDA has recently received several submissions from individuals and various organizations concerning the labeling of irradiated foods. The following list summarizes these submissions.

1. “Identifying, Addressing and Overcoming Consumer Concerns.” A Roundtable on Food Irradiation, convened by Public Voice for Food Health Policy, the National Food Processors Association, and the International Food Information Council, February 18 and 19, 1998 (Ref. 7). This report summarizes the discussion by invited participants regarding consumer concerns about food irradiation. According to the report:

Roundtable participants generally agreed that irradiated foods should continue to be labeled, subject to existing exceptions. However, participants were open to variations on existing label language—such as cold pasteurization (irradiation)—that would provide an informative, truthful and non-threatening way to notify consumers that a particular product has been irradiated.

2. A letter from Senator Tom Harkin, dated January 21, 1998 (Ref. 8), and FDA's March 27, 1998, response to Senator Harkin (Ref. 9). Senator Harkin expresses concern that the current labeling requirements "foster baseless fears," and requests that FDA proceed quickly to "finalize a new rule providing for more appropriate labeling of foods processed with ionizing irradiation." Senator Harkin also suggests the use of alternative terms as "cold pasteurization" or "electronic pasteurization" in any irradiation disclosure statement.

3. An excerpt from "Food Labeling for the 21st Century: A Global Agenda for Action," A Report by the Center for Science in the Public Interest (CSPI), May 1998 (Ref. 10). This report includes a discussion of the labeling of irradiated foods and food ingredients. As part of the report's recommendations, CSPI states that,

Any foods, or any foods containing ingredients, that have been treated by irradiation should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale.

4. A citizen petition from the National Food Processors Association, dated May 21, 1998 (Ref. 11). This petition requests that FDA remove the labeling requirements for irradiated foods, stating, among other things, that "the required radiation statement causes consumer concern about a non-existent hazard, at the expense of discouraging a process that can mitigate very real safety hazards."

5. A letter from Burrell J. Smittle, Florida Linear Accelerator, dated September 3, 1998 (Ref. 12), expressing the opinion that no radiation disclosure statement should be required.

6. A letter from Consumer Alert, dated September 15, 1998 (Ref. 13), stating support for the position that the radiation disclosure statement should not be more prominent than the declaration of ingredients.

7. A letter from the National Consumers League, dated September 16, 1998 (Ref.14), expressing the opinion that the radiation disclosure statement should be more prominent than the declaration of ingredients.

8. A section of the ‘ ‘Codex General Standard for Labelling of Prepackaged Foods,” Codex Alimentarius Commissions 1995 (Ref. 15) and a summary list of the labeling requirements for irradiated foods in various countries (Ref. 16). Under the provisions of the Codex standard, a written radiation disclosure statement is to be used on the label of irradiated foods; the use of the radura symbol, however, is optional. Of the countries included in the summary list, all require a label statement, and none rely on the radura logo alone. In addition, most of these countries require that the label statement use wording similar to that required by FDA’s regulations (i.e., the use of a word comparable to ‘ ‘irradiation” or “radiation’ ‘),

IV. Request for Comments

As previously discussed, FDA is publishing this ANPRM to request public comment on whether revisions of the current labeling requirements for irradiated foods are needed to accomplish the objectives outlined in the FDAMA Joint Statement and the labeling requirements of the act, and, if so, what form such revisions might take. In keeping with the FDAMA Joint Statement, FDA is soliciting comments on two issues: (1) Whether the wording of the current radiation disclosure statement should be revised, and (2) whether such labeling requirements should expire at a specified date in the future. To better assist FDA in formulating specific revisions that would accomplish the objectives outlined in the FDAMA Joint Statement and also satisfy the requirements of the act and the agency’s other regulations regarding the labeling of food in general, the agency encourages interested persons to address the following questions in their comments:

(1) Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

³ The Codex Alimentarius Commission is an international consensus standards body organized under the auspices of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

(2) How do consumers perceive the current radiation disclosure statement—as informational, as a warning, or as something else’?

(3) Does the wording of the current radiation disclosure statement cause “inappropriate anxiety” among consumers? What are examples of “inappropriate anxiety”?

(4) What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

(5) Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods? Are consumers misled by the presence of such a statement?

(6) With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement’? Would consumers be misled by the presence of such a statement?

(7) What is the level of direct consumer experience with irradiated foods that are labeled as such?

(8) What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation’?

(9) What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?

(10) Do consumers readily recognize the radura logo?

(11) Do consumers understand the logo to mean that a food has been irradiated?

(12) Do consumers perceive the radura logo as informational, as a warning, or as something else?

(13) Should any requirement for a radiation disclosure statement expire at a specified date in the future?

(14) If so, on what criteria should the expiration be based?

(15) If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

FDA strongly encourages the submission of the results of any focus group or other consumer perception studies regarding irradiated foods and the labeling of such foods. In addition, FDA encourages those persons who suggest a revision of the radiation disclosure statement also to submit a brief discussion of the advantages of their suggestion over the current statement. Finally, FDA encourages interested persons to submit information regarding the prevalence of irradiated foods in the marketplace and information regarding the level of consumer experience and awareness of irradiated foods and irradiation processing.

V. Comments

Interested persons may, on or before *(insert date 90 days after date of publication in the Federal Register)*, submit to the Dockets Management Branch, written comments on this ANPRM and supporting material. Two copies of any comment are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Conference Report on S. 830, Food and Drug Administration Modernization Act of 1997, 143 Cong. Rec. H10452, 10477 (November 9, 1997).

2. "Irradiation in the Production, Processing, and Handling of Food; Proposed Rule," FDA, **Federal Register**, February 14, 1984 (49 FR 57 14).

3. “Irradiation in the Production, Processing, and Handling of Food; Final Rule,” FDA, **Federal Register**, April 18, 1986 (51 FR 13376).
4. “Irradiation in the Production, Processing, and Handling of Food; Final Rule; Denial of Request for Hearing and Response to Objection,” FDA, **Federal Register**, December 30, 1988 (53 FR 53176).
5. “Irradiation in the Production, Processing, and Handling of Food; Final Rule,” FDA, **Federal Register**, April 18, 1988 (53 FR 12757),
6. “Irradiation in the Production, Processing, and Handling of Food; Final Rule,” FDA, **Federal Register**, April 18, 1990 (55 FR 14415).
7. “Identifying, Addressing and Overcoming Consumer Concerns.” A Roundtable on Food Irradiation, convened by Public Voice for Food Health Policy, the National Food Processors Association, and the International Food Information Council, February 18 and 19, 1998.
8. Letter from Senator Tom Harkin to Michael Friedman, FDA, January 21, 1998.
9. Letter from Diane E. Thompson, FDA, to Senator Tom Harkin, March 27, 1998,
10. ‘ ‘Food Labeling for the 21st Century: A Global Agenda for Action,” by the Center for Science in the Public Interest, May 1998.
11. Citizen Petition from John R. Cady, National Food Processors Association to FDA, May 21, 1998.
12. Letter from Burrell J. Smittle, Florida Linear Accelerator to Dockets Management Branch, FDA, September 3, 1998.
13. Letter from Barbara Rippel, Consumer Alert to Dockets Management Branch, FDA, September 15, 1998.
14. Letter from Linda F. Golodner, National Consumers League to Dockets Management Branch, FDA, September 16, 1998.

15. Codex General Standard for Labelling of Prepackaged Foods, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Rome, 1995.

16. "Present Status of Labelling Requirements in Various Countries," October 16, 1998.

Dated: February 8, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

